Message

From: MAUNE, ONA [AG/1005] [ona.maune@bayer.com]

Sent: 3/14/2019 4:01:25 PM

To: Benbow, Bethany [benbow.bethany@epa.gov]

CC: Schmid, Emily [Schmid.Emily@epa.gov]; james.m.nyangulu@monsanto.com

Subject: RE: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX_2018_003798)

Attachments: 071995-00037.20190314.pdf; 71995-37 Master Label REV1 Highlighted-Mar142019.pdf

Dear Beth,

Thanks for your review comments for the EPA Reg. No. 71995-37 master label amendment. We've provided some additional clarification below for your consideration in response to the highlighted items. Additions (i.e. first aid) and corrections were made where noted; as well as minor revisions (additions in blue text). I've attached a final clean label pdf (071995-00037.20190314); as well as a marked/highlighted label copy for your reference.

- 1) As requested, moved the triclopyr annual rate application restriction from 'How To Apply' and 'When To Apply' sections into the 'APPLICATION RESTRICTIONS' section (pg. 5).
- 2) Wild Blackberry directions for use (pg. 5), reordered for additional clarity. We believe consumers understand after the product kills the plant that the dead canes should be removed.
- 3) 'When To Apply' section (pg. 5): 'For best results, apply during warm sunny weather above 60° F' [to accelerate systemic movement from foliage to roots].' As this is a consumer product, this statement expands on the first bullet 'Apply when weeds are actively growing.' We want consumers to apply product during 'optimal growing conditions' for this non-selective herbicide enabling glyphosate uptake by the foliage & translocation to the root based on our efficacy field testing/ claims. We do not expect significant volatilization with this formula, as it has low vapor pressure, glyphosate in form of IPA salt and non-volatile potential inert ingredients (mostly water). Also, this concentrate product is diluted 6 fl oz per gallon of water and used by homeowners for spot treatment of weeds/brush in their yard.
- 4) 'Users Safety Recommendations' (pg. 6): per Triclopyr RED, keep as stated. If we market a co-pack of the concentrate with the RTU product, this required text must match.
- 5) 'Promotional Offering Options' section (pg. 16): added product references and notes to the reviewer. All products, including samples, of <u>this</u> registered product will include EPA required labeling.
- 6) Recyclable bottle (pg. 17): residential/household use products are exempt from the residue removal instruction requirement per 40 CFR 156.14(c). The Disposal section on this label states "If Empty: Place in trash or offer for recycling, if available."

I can be reached directly to discuss any outstanding questions or concerns. I look forward to trying to get this pending label amendment finalized. Thanks in advance for all your assistance.

Kindest Regards, Ona

Ona Maune

Lawn & Garden Regulatory Affairs Manager

Bayer US
Monsanto Company
Crop Science Division
700 Chesterfield Parkway West FF4B
Chesterfield, Missouri, 63017, USA

Office: +1 636.737.9577

E-mail: <u>ona.maune@bayer.com</u>
Web: <u>http://www.bayer.com</u>

From: Benbow, Bethany <benbow.bethany@epa.gov>

Sent: Monday, February 25, 2019 2:24 PM

To: MAUNE, ONA [AG/1005] < ona.maune@bayer.com>

Cc: NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>; Schmid, Emily <Schmid.Emily@epa.gov>;

Baris, Reuben <Baris.Reuben@epa.gov>

Subject: RE: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX_2018_003798)

Good afternoon, Ona,

Attached is a review of the proposed label amendment for MON 78736 Herbicide ML. Please feel free to contact me with any questions in regard to this review. Email is the best way to contact me since I am working afternoons and evenings from home at this time.

You can send a clean and highlighted version of the revised label directly to me in response to this email.

Thank you for your patience.

Beth Benbow

Beth Benbow Biologist, M.S. Risk Manager, Registration Division Office of Pesticide Programs Environmental Protection Agency

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Sent: Thursday, February 7, 2019 2:33 PM **To:** Schmid, Emily <Schmid.Emily@epa.gov>

Cc: james.m.nyangulu@monsanto.com; Benbow, Bethany <benbow.bethany@epa.gov>

Subject: RE: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX 2018 003798)

Thanks Emily,

We're glad to hear she's still part of the team. We really appreciate your prompt response and look forward to an update from Beth.

Kindest Regards, Ona

From: Schmid, Emily <<u>Schmid.Emily@epa.gov</u>> Sent: Thursday, February 07, 2019 12:51 PM

To: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Cc: NYANGULU, JAMES M [AG/1920] < james.m.nyangulu@monsanto.com >

Subject: RE: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX 2018 003798)

Hi Ona,

Luckily for us, Beth is actually still with our branch. She works part time at night but is still the reviewer assigned to this action. I have copied her so she can reply with an update.

Best regards,

Emily

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Sent: Thursday, February 07, 2019 12:00 PM **To:** Schmid, Emily <<u>Schmid.Emily@epa.gov</u>> **Cc:** james.m.nyangulu@monsanto.com

Subject: FW: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX_2018_003798)

Hi Emily,

I understand from James your team was recently reorganized and unfortunately it appears Beth Benbow is no longer part of the PM25 reviewer team. This Master Label Amendment (EPA# 71995-37) had been assigned to Beth at the end of November; however I had not received any feedback beyond her reply below. For clarification, we hadn't made any changes to the label submitted 5/14/2018; I had only included the cover memo in the email to Beth for reference. Therefore, I wanted to follow-up with you directly on the status and which reviewer this action may have been transferred. We understand your team is significantly understaffed, but we really need to be able to implement revised labels in the market.

Please reach out to me directly if you have any questions. As always, thanks in advance for your assistance.

Kindest Regards, Ona

Ona Maune | Chemistry Federal Regulatory Affairs Manager | Lawn & Garden 636,737,9577 office ona.maune@bayer.com

From: Benbow, Bethany

benbow.bethany@epa.gov>

Sent: Tuesday, December 04, 2018 7:36 PM

To: MAUNE, ONA [AG/1005] < ona.maune@bayer.com>

Cc: NYANGULU, JAMES M [AG/1920] < james.m.nyangulu@monsanto.com >

Subject: RE: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX 2018 003798)

Thank you Ona,

I will review this latest version of the label and get back to you when possible.

Regards,

Beth Benbow

Beth Benbow Biologist, M.S. Risk Manager, Registration Division Office of Pesticide Programs Environmental Protection Agency

From: MAUNE, ONA [AG/1005] < ona.maune@bayer.com>

Sent: Tuesday, December 4, 2018 10:27 AM

To: Benbow, Bethany <benbow.bethany@epa.gov>

Cc: james.m.nyangulu@monsanto.com

Subject: FW: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX_2018_003798)

Good Morning Beth,

I'm reaching out to you regarding the status in your queue of the pending Master Label amendment EPA# 71995-37 submitted 5/14/2018. We would like to implement revised labels for this residential concentrated non-selective herbicide product consistent with the corresponding ready-to-use product EPA# 71995-36, which was previously

approved by the Agency **5/22/2017**. Please note the key revisions are outlined in the attached cover memo, many of which are the same as the current EPA# 71995-36 master label.

Please reach out to me directly if you have any questions. As always, thanks in advance for your assistance.

Kindest Regards, Ona

Ona Maune | Chemistry Federal Regulatory Affairs Manager | Lawn & Garden 636.737.9577 office ona.maune@bayer.com

From: MAUNE, ONA [AG/1005]

Sent: Tuesday, November 27, 2018 2:03 PM **To:** Schmid, Emily Schmid.Emily@epa.gov

Cc: NYANGULU, JAMES M [AG/1920] < iames.m.nyangulu@monsanto.com >

Subject: RE: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX_2018_003798)

Thanks Emily,

I'll follow-up with Beth next week, which will give her a chance to add it to her queue. Appreciate your quick response.

Kindest Regards, Ona

From: Schmid, Emily [mailto:Schmid.Emily@epa.gov]

Sent: Tuesday, November 27, 2018 1:34 PM

To: MAUNE, ONA [AG/1005] < ona.maune@bayer.com>

Subject: RE: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX_2018_003798)

Hi Ona,

This one has just been assigned to Beth Benbow. She hasn't had a chance to log it in yet but I know her backlog isn't too bad so she should be able to get to it fairly soon.

I hope this helps.

Best regards, Emily

From: MAUNE, ONA [AG/1005] <ona.maune@bayer.com>

Sent: Tuesday, November 27, 2018 1:42 PM **To:** Schmid, Emily <<u>Schmid.Emily@epa.gov</u>> **Cc:** james.m.nyangulu@monsanto.com

Subject: EPA# 71995-37 MON 78736 Herbicide ML Amendment: Submitted 5/14/2018 (CDX_2018_003798)

Good Afternoon Emily,

I wanted to follow-up with you on the status of a pending Master Label amendment **EPA# 71995-37** submitted **5/14/2018**. We understand that your team is short staffed and there's a significant backlog of non-PRIA fast track amendments. However, we would like to implement revised labels for this residential concentrate product consistent with the corresponding ready-to-use product EPA# 71995-36, which was previously approved by the Agency 5/22/2017.

Any feedback regarding the expected timing would be helpful to share with our business folks. I've included the ePortal CDX information below and attached the cover memo. Please let me know if you have questions.

As always, thanks in advance for your assistance. Kindest Regards, Ona

Ona Maune | Chemistry Federal Regulatory Affairs Manager | Lawn & Garden 636.737 9577 office ona.maune@bayer.com

From: helpdesk@epacdx.net [mailto:helpdesk@epacdx.net]

Sent: Tuesday, May 15, 2018 7:55 AM

To: AFFAIRS, REGULATORY [AG/1000] < regulatory.affairs@monsanto.com >

Subject: CDX PSP Package Status Update: Milestone 1 Completed

The status of your PSP package (71995-37_Master.Label.Amendment_20180514) is: Milestone 1 Completed.

Below are the application(s) included in this package and their tracking number(s):

Sec3-Amend-000001: CDX 2018 003798

Company Name: MONSANTO COMPANY

Company Number: 71995

If you have questions concerning this message, you may contact the CDX Help Desk by email at helpdesk@epacdx.net or by calling the CDX Technical Support Staff through our toll free telephone support on (888) 890-1995 between Monday through Friday from 8:00 am to 6:00 pm EST/EDT. For International callers, the CDX Help Desk can also be reached at (970) 494-5500.

CDX Homepage

https://cdx.epa.gov

United States Environmental Protection Agency - Central Data Exchange

This system contains confidential and copyrighted information. Access to the system is limited to users only and only for approved business purposes.

Anyone obtaining access to and using this system acknowledges that all information on this system including but not limited to electronic mail, word processing, directories and files, constitutes private property belonging to the Company.

Anyone using or viewing this system is further advised that the use of this system may be recorded and the information contained herein maybe monitored, retrieved and reviewed if, in the company's sole discretion, there is a business reason to do so.

If improper activity or use is suspected, all available information may be used by the Company for possible disciplinary action, prosecution, civil claim or any remedy or lawful purpose.

This system contains confidential and copyrighted information. Access to the system is limited to users only and only for approved business purposes.

Anyone obtaining access to and using this system acknowledges that all information on this system including but not limited to electronic mail, word processing, directories and files, constitutes private property belonging to the Company.

Anyone using or viewing this system is further advised that the use of this system may be recorded and the information contained herein maybe monitored, retrieved and reviewed if, in the company's sole discretion, there is a business reason to do so.

If improper activity or use is suspected, all available information may be used by the Company for possible disciplinary action, prosecution, civil claim or any remedy or lawful purpose.

This system contains confidential and copyrighted information. Access to the system is limited to users only and only for approved business purposes.

Anyone obtaining access to and using this system acknowledges that all information on this system including but not limited to electronic mail, word processing, directories and files, constitutes private property belonging to the Company.

Anyone using or viewing this system is further advised that the use of this system may be recorded and the information contained herein maybe monitored, retrieved and reviewed if, in the company's sole discretion, there is a business reason to do so.

If improper activity or use is suspected, all available information may be used by the Company for possible disciplinary action, prosecution, civil claim or any remedy or lawful purpose.

The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.